

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
15 August 2002 (15.08.2002)

PCT

(10) International Publication Number
WO 02/062270 A1

(51) International Patent Classification⁷: A61F 2/24, 2/06

(21) International Application Number: PCT/EP01/10371

(22) International Filing Date:
8 September 2001 (08.09.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/775,677 5 February 2001 (05.02.2001) US

(71) Applicants and

(72) Inventors: SOLEM, Jan, Otto [NO/CH]; Wallenruts-
trasse 14, CH-8234 Stetten (CH). KIMBLAD, Per, Ola
[SE/SE]; Saturnusgatan 9, S-224 57 Lund (SE).

CN, CO, CR, CU, CZ (utility model), DE (utility model),
DK (utility model), DM, DZ, EC, EE (utility model), ES,
FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL,
IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU,
LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH,
PL, PT, RO, RU, SD, SE, SG, SI, SK (utility model), SL,
TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF,
CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD,
TG).

Published:

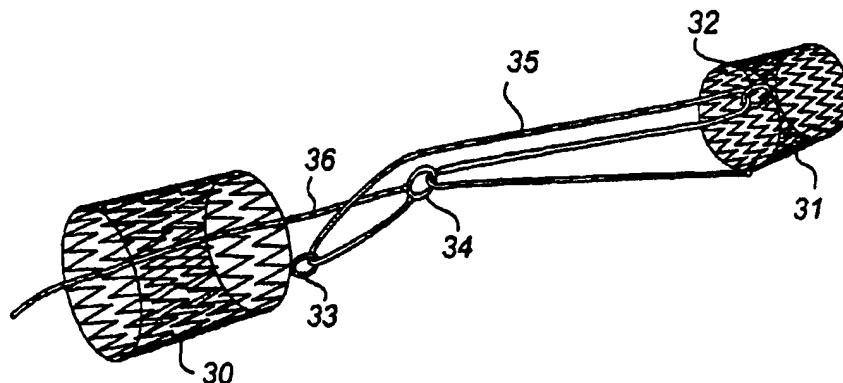
— with international search report

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(74) Agent: AWAPATENT AB; Box 5117, S-200 71 Malmö
(SE).

(81) Designated States (national): AE, AG, AL, AM, AT (uti-
lity model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH,

(54) Title: DEVICE FOR TREATMENT OF MITRAL INSUFFICIENCY



(57) Abstract: A device for treatment of mitral annulus dilatation comprises an elongate body having two states. In a first of these states the elongate body is insertable into the coronary sinus and has a shape adapting to the shape of coronary sinus. When positioned in the coronary sinus, the elongate body is transferable to the second state assuming a reduced radius of curvature, whereby the radius of curvature of the coronary sinus and the radius of curvature as well as the circumference of the mitral annulus is reduced. The elongate body comprises a distal stent section, a proximal stent section and control wires for reducing the distance between the distal and proximal stent sections.

BEST AVAILABLE COPY

WO 02/062270 A1

DEVICE FOR TREATMENT OF MITRAL INSUFFICIENCY

BACKGROUND OF THE INVENTION

Technical Field of the Invention

The present invention generally relates to a device
5 for treatment of mitral insufficiency and, more specifically, for treatment of dilatation of the mitral annulus.

Description of the Prior Art

Mitral insufficiency can result from several causes, such as ischemic disease, degenerative disease of the mitral apparatus, rheumatic fever, endocarditis, congenital heart disease and cardiomyopathy. The four major structural components of the mitral valve are the annulus, the two leaflets, the chordae and the papillary muscles. Any one or all of these in different combinations may be injured and create insufficiency. Annular dilatation is a major component in the pathology of mitral insufficiency regardless of cause. Moreover, many patients have a mitral insufficiency primarily or only due to posterior annular dilatation, since the annulus of the anterior leaflet does not dilatate because it is anchored to the fibrous skeleton of the base of the heart.

Studies of the natural history of mitral insufficiency have found that totally asymptomatic patients with severe mitral insufficiency usually progress to severe disability within five years. At present the treatment consists of either mitral valve replacements or repair, both methods requiring open heart surgery. Replacement can be performed with either mechanical or biological valves.

The mechanical valve carries the risk of thromboembolism and requires anticoagulation, with all its potential hazards, whereas biological prostheses suffer from limited durability. Another hazard with replacement is
5 the risk of endocarditis. These risks and other valve related complications are greatly diminished with valve repair.

Mitral valve repair is theoretically possible if an essentially normal anterior leaflet is present. The basic
10 four techniques of repair include the use of an annuloplasty ring, quadrangular segmental resection of diseased posterior leaflet, shortening of elongated chordae, and transposition of posterior leaflet chordae to the anterior leaflet.

15 Annuloplasty rings are needed to achieve a durable reduction of the annular dilatation. All the common rings are sutured along the posterior mitral leaflet adjacent to the mitral annulus in the left atrium. The Duran ring encircles the valve completely, whereas the others are
20 open towards the anterior leaflet. The ring can either be rigid, like the original Carpentier ring, or flexible but non-elastic, like the Duran ring or the Cosgrove-Edwards ring.

Effective treatment of mitral insufficiency currently requires open-heart surgery, by the use of total
25 cardiopulmonary by-pass, aortic cross-clamping and cardioplegic cardiac arrest.

To certain groups of patient, this is particular hazardous. Elderly patients, patients with a poor left
30 ventricular function, renal disease, severe calcification of the aorta, previous cardiac surgery or other concomitant diseases, would in particular most likely benefit from a less invasive approach, even if repair is not com-

plete. The current trend towards less invasive coronary artery surgery, without cardiopulmonary by-pass, as well as PTCA will also call for a development of a less invasive method for repair of the often concomitant mitral insufficiency.

SUMMARY OF THE INVENTION

Therefore, a first object of the present invention is to provide a device for treatment of mitral insufficiency without the need for cardiopulmonary by-pass and without opening of the chest and heart.

A second object of the invention is to provide reduction of the mitral annulus using only catheter based technology.

According to the present invention, a device for treatment of mitralis insufficiency comprises an elongate body having such dimensions as to be insertable into the coronary sinus and having two states, in a first state of which the elongate body has a shape that is adaptable to the shape of the coronary sinus, and to the second state of which the elongate body is transferable from the said first state assuming a reduced radius of curvature, whereby the radius of curvature of the coronary sinus is reduced as well as the circumference of the mitral valve annulus, when the elongate body is positioned in the coronary sinus. More precisely, the elongate body comprises a distal stent section, a proximal stent section and control wires for reducing the distance between the distal and proximal stent sections.

Thus, means are provided for the transfer of the elongate body to the second state by shortening it from a larger radius of curvature to a smaller radius of curvature.

The control wires may comprise a first wire and means for guiding said first wire in a course extending two times between the distal and proximal stent sections, when the distance therebetween is at a maximum, and extending at least three times between the distal and proximal stent sections, when the distance therebetween is at a minimum.

To accomplish changes in the course, the guiding means preferably comprises a first eyelet fixed to one of the distal and proximal stent sections, a second eyelet fixed to the other of the distal and proximal stent sections, and a third eyelet positioned between the distal and proximal stent sections, said first wire having a first end fixed to said one of the distal and proximal stent section and extending therefrom via the third eyelet, the first eyelet and the second eyelet back to the third eyelet where a second end of the first wire is fixed. By this structure the maximum distance between the two stent sections will be about 1.5 times the minimum distance between the two stent sections.

A larger quotient may be obtained by extending the first wire from the first eyelet at least once more via the third eyelet and the first eyelet before finally extending the first wire via the second eyelet back to the third eyelet where the second end of the first wire is fixed.

In order to reduce the distance between the distal stent section and the proximal stent section, said first eyelet is preferably fixed to the distal stent section and said control wires comprise a second wire extending through the third eyelet and as a double wire proximally therefrom out of the coronary sinus and out of the human body. As an alternative to this second wire, a single

wire may be used having an end releasably fixed to the third eyelet and extending as a single wire proximally therefrom out of the coronary sinus and out of the human body. However, to be able to also increase the distance
5 between the distal stent section and the proximal stent section, said control wires may comprise a third wire extending through the third eyelet and as a double wire distally to and through the first eyelet and then as a double wire proximally therefrom out of the coronary sinus and out of the human body.
10

Alternatively, the distance between the distal stent section and the proximal stent section may be reduced by fixing the first eyelet to the proximal stent section. Then, said control wires should comprise a second wire
15 extending through the third eyelet and as a double wire distally to and through the first eyelet and then as a double wire proximally therefrom out of the coronary sinus and out of the human body. In order to be able to increase the distance between the distal stent section and
20 the proximal stent section in this case, the control wires should comprise a third wire extending through the third eyelet and as a double wire proximally therefrom out of the coronary sinus and out of the human body.

It should be noted that when the proximal and distal
25 stent sections have been fixed relative to the coronary sinus and the distance between them thereafter has been finally adjusted to a desired value, the second and the third wires may in both the described alternatives be withdrawn from the coronary sinus by pulling one of their
30 ends positioned outside of the coronary sinus and outside of the human body.

In preferred embodiments of the device, a cover encloses the wires in their courses between the distal and

proximal stent sections so as to eliminate the risk that the wires will injure the coronary sinus by cutting into its internal surfaces.

The cover may comprise one or more plastic sheaths
5 and may also comprise one or more helical wires.

In an alternative embodiment, the device for treatment of mitral annulus dilatation comprises an elongate body having such dimensions as to be insertable into the coronary sinus and having two states, in a first of which
10 the elongate body has a shape that is adaptable to the shape of the coronary sinus, and to the second of which the elongate body is transferable from said first state assuming a reduced radius of curvature, whereby the radius of curvature of the coronary sinus is reduced as
15 well as the circumference of the mitral valve annulus, when the elongate body is positioned in the coronary sinus, said elongate body comprising at least one stent section at a distance from each end of the elongate body, said stent section providing a reduction of its length
20 when expanded in situ in the coronary sinus, whereby the elongate body is shortened and bent to a smaller radius of curvature.

Preferably, the elongate body of this embodiment comprises a proximal stent section, a distal stent section and a central stent section, the distal and proximal
25 stent sections being expandable prior to the central stent section. Obviously, this will result in a reduction of the distance between the proximal and distal stent sections. Further, the proximal and distal stent sections
30 should be expandable without substantial length reduction.

Thus, the present invention takes advantage of the position of the coronary sinus being close to the mitral

annulus. This makes repair possible by the use of current catheter-guided techniques.

The coronary veins drain blood from the myocardium to the right atrium. The smaller veins drain blood directly into the atrial cavity, and the larger veins accompany the major arteries and run into the coronary sinus which substantially encircles the mitral orifice and annulus. It runs in the posterior atrioventricular groove, lying in the fatty tissue between the left atrial wall and the ventricular myocardium, before draining into the right atrium between the atrial septum and the post-Eustachian sinus.

In an adult, the course of the coronary sinus may approach within 5-15 mm of the medial attachment of the posterior leaflet of the mitral valve. Preliminary measurements performed at autopsies of adults of normal weight show similar results, with a distance of $5,3 \pm 0,6$ mm at the medial attachment and about 10 mm at the lateral aspect of the posterior leaflet. The circumference of the coronary sinus was $18,3 \pm 2,9$ mm at its ostium (giving a sinus diameter of the septal aspect of the posterior leaflet of $5,8 \pm 0,9$ mm) and $9,7 \pm 0,6$ mm along the lateral aspect of the posterior leaflet (corresponding to a sinus diameter of $3,1 \pm 0,2$ mm).

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood by the following description of preferred embodiments referring to the appended drawings, in which

FIG. 1 is a cross-sectional view of a part of a heart,

FIGS 2 and 3 are schematic views of a first embodiment of a device according to the present invention,

FIGS 4-6 are schematic views illustrating an instrument, which may be used when positioning the device shown in FIGS 2 and 3 in the coronary sinus,

FIG. 7 is a partial, enlarged view of the first embodiment shown in FIG. 2.

FIGS 8 and 9 are schematic views illustrating the positioning of the device of FIGS 2 and 3 in the coronary sinus,

FIGS 10 and 11 are schematic views illustrating the positioning of a second embodiment of the device according to the present invention in the coronary sinus,

FIGS 12 and 13 are schematic views illustrating the positioning of a third embodiment of the device according to the present invention in the coronary sinus.

FIG 14 illustrates a fourth embodiment of the device according to the present invention.

FIG. 15 is a schematic view illustrating a preferred operation of the fourth embodiment.

FIG. 16 is a schematic view illustrating the operation of a fifth embodiment of the device according to the present invention.

FIG. 17 illustrates a sixth embodiment of the device according to the present invention.

FIG. 18 illustrates a further modification of the embodiments of FIGS 14-17.

FIGS 19 and 20 illustrate a seventh embodiment of the device according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG 1 is a cross-sectional view through the heart area of the posterior atrioventricular groove 1, which is filled with fatty tissue. It shows the posterior leaflet 2 of the mitral valve and the adjoining parts 3, 4 of the

atrial myocardium and the ventricular myocardium. The coronary sinus 5 is shown close to the mitral annulus 6 and behind the attachment 7 of the posterior leaflet 2. Since the coronary sinus 5 substantially encircles the mitral annulus 6, a reduction of the radius of curvature of the bent coronary sinus 5 also will result in a diameter and circumference reduction of the mitral annulus 6.

The device of FIG. 2 comprises an elongate body 8 made of memory metal, e.g. Nitinol, or other similar material which has a memory of an original shape, illustrated in FIG. 3, and can be temporary forced into another shape, illustrated in FIG. 2. This elongate body 8 comprises one, two or more memory metal strings 9 of helical or other shape so as to fit together and be able of permitting the movements described below. Along the elongate body 8 several hooks 10 are fastened so as to extend radially out therefrom. These hooks 10 are covered by a cover sheath 11 in FIG. 2.

The elongate body 8 is forced into a stretched or extended state by means of a stabilizing instrument 12 shown in FIG. 4. This instrument 12 has two arms 13 at a distal end 14 of a rod 15 and a locking means 16 at a proximal end of the rod 15. The distance between the ends of the rod 15 corresponds to the desired length of the elongate body 8 when being inserted into the coronary sinus 5.

The arms 13 are free to move between the position shown in FIG. 4 and a position in alignment with the rod 15, as shown in FIG. 6. The locking means 16 has two locking knobs 17, which are pressed radially outwards from the rod 15 by two spring blades 18. Thus, the elongated body 8 can be pushed over the rod 15 of the stabilizing instrument 12, then stretched between the arms 13

10

and the knobs 17, and finally locked in its stretched state on the stabilizing instrument 12 between the arms 13 and the knobs 17, as illustrated in FIG. 5.

The rod 15 may be a metal wire which is relatively
5 stiff between the distal end 14 and the locking means 16 but still so bendable that it will follow the shape of the coronary sinus 5. Proximally of the locking means 16 the metal wire of the stabilizing instrument 11 is more pliable to be able to easily follow the bends of the
10 veins.

The above-described elongate body 8 is positioned in the coronary sinus 5 in the following way:

An introduction sheath (not shown) of synthetic material may be used to get access to the venous system.
15 Having reached access to the venous system, a long guiding wire (not shown) of metal is advanced through the introduction sheath and via the venous system to the coronary sinus 5. This guiding wire is provided with X-ray distance markers so that the position of the guiding wire
20 in the coronary sinus 5 may be monitored.

The elongate body 8 is locked onto the stabilizing instrument 12, as shown in FIG. 5, and introduced into the long cover sheath 11 of synthetic material. This aggregate is then pushed through the introduction sheath
25 and the venous system to the coronary sinus 5 riding on the guiding wire. After exact positioning of the elongate body 8 in the coronary sinus 5, as illustrated in FIG. 8 where the mitral valve 19 is shown having a central gap 20, the cover sheath 11 is retracted exposing the elongate body 8 within the coronary sinus 5. This maneuver
30 allows the hooks 10 on the elongate body 8 to dig into the walls of the coronary sinus 5 and into the heart. The elongate body 8 is still locked on to the stabilizing in-

11

strument 12 such that the hooks 10 engage the walls of the coronary sinus 5 in the stretched or extended state of the elongate body 8.

A catheter 21, shown in FIG. 6, is pushed forward on the guiding wire and the rod 15 for releasing the elongate body 8 from the locking means 16 by pressing the spring blades 18 towards the rod 15. This movement releases the knobs 17 as well as the arms 13 from engagement with the elongate body 8 which contracts as illustrated in FIG. 9, thereby shortening the radius of curvature of the coronary sinus. As a result, the mitral valve annulus 6 shrinks moving the posterior part thereof forward (shown by arrows in FIG. 9). This movement reduces the circumference of the mitral valve annulus 6 and thereby closes the central gap 20.

FIG. 7 illustrates a part of an arrangement of the wires 9 and the hooks 10 along a peripheral part of the elongate body 8, whereby the elongate body 8 will be asymmetrically contracted resulting in a bending thereof when interconnecting parts 22 of at least some of the hooks 10 are shortened to an original shape.

FIGS 10 and 11 illustrate an alternative embodiment of an elongate body 8', which is a solid wire in the shape of an open U-shaped ring that will engage the wall of the coronary sinus 5 most adjacent to the mitral valve annulus 6 when inserted into the coronary sinus 5. The elongate body 8' consists of a memory metal material which when reverting to its original shape will bend as illustrated in FIG. 11. The return of the open ring 8' to its original shape may be initiated in several ways, as is obvious to the man skilled in the art.

The third embodiment of the elongate body 8'', illustrated in FIGS 12 and 13, comprises three stent sections

12

23-25 positioned at one end of the elongate body 8", at the middle thereof and at the other end of the elongate body 8", respectively. These stent sections 23-25 may be positioned in the coronary sinus 5 as illustrated by conventional means, such that their positions are fixed. They are connected by wires 26, 27, which may be maneuvered from outside the vein system such that the distances between the adjacent stent sections 23, 24 and 24, 25 are reduced. More specifically, these distances are reduced asymmetrically, i.e. more on the side of coronary sinus 5 most adjacent to the posterior part of the mitral valve annulus 6. Thereby, the elongate body 8" is bent, as illustrated in FIG. 13, and presses the coronary sinus 5 against the mitral valve annulus 6 closing the gap 20.

15 A fourth embodiment of the device is shown in FIG. 14 as comprising two stent sections, more precisely a proximal stent section 30 and a distal stent section 31. The fourth embodiment further comprises a first eyelet 32, which is fixed to a preferably proximal part of the the distal stent section 31, a second eyelet 33, which is fixed to a preferably distal part of the proximal stent section 30, and a third eyelet 34, which is positioned between the proximal and distal stent sections 30, 31. These sections 30, 31 are joined by a wire 35, one end of which is fixed to the the distal stent section 31. The wire 35 may be fixed to the distal stent section 31 at a proximal point, as shown in FIG. 14, or at a more distal point up to the distal end of the distal stent section 31.

30 From the distal stent section 31 the wire 35 extends to and through the third eyelet 34 and then back towards the distal stent section 31 to and through the first eyelet 32. From the first eyelet 32 the wire 35 then extends

to and through the second eyelet 33 and then finally to the third eyelet 34, the other end of the wire 35 being fixed to this third eyelet 34.

By moving the third eyelet 34 towards the proximal stent section 30, the distance between the proximal and distal stent sections 30, 31 will be reduced. On the contrary, by moving the third eyelet 34 towards the distal stent section 31, the distance between the proximal and distal stent sections may be increased. However, such increase will require some means pushing the distal stent section 31 in a distal direction away from the proximal stent section 30 or pulling the proximal stent section in a proximal direction away from the distal stent section 31.

The distance between the proximal and distal stent sections 30, 31 will reach a maximum when the third eyelet 34 is positioned close to the distal stent section 31 and will reach a minimum when the third eyelet 34 is positioned close to the proximal stent section 30.

The third eyelet 34 may be moved towards the proximal stent section 30 by means of a single wire 36, which has an end releasably fixed to the third eyelet 34 and extends proximally therefrom through the proximal stent section 30 and further proximally out of the coronary sinus 5, through the vein system and out of the human body.

In a preferred embodiment schematically illustrated in FIG. 15, a second wire 37 extends through the third eyelet 34 and further extends as a double wire proximally from the third eyelet 34, through the proximal stent section 30 and the coronary sinus 5 and then out of the body. The third eyelet 34 will be moved proximally by simultaneous pulling both ends of the second wire 37 outside of the body. When the desired position of the third

14

eyelet 34 is reached, the second wire 37 may easily be removed through the vein system by pulling only one of its ends outside the body.

As illustrated in FIG. 15, a third wire 38 may be extended through the third eyelet 34. Therefrom it extends as a double wire distally to and through the first eyelet 32 and then this double wire extends proximally from the first eyelet 32 (or a further eyelet fixed to the proximal end of the distal stent) through the proximal stent section 30 and finally the double wire 38 extends proximally through the coronary sinus 5 and out of the human body. By pulling both ends of this third wire 38 outside of the body, the third eyelet 34 will allow a movement of the proximal and distal stent sections 30, 31 away from each other. By means of the second wire 37 and the third wire 38 the position of the third eyelet 34 may be adjusted repeatedly until a desired position is attained. The third wire 38 may be removed in the same manner as the second wire 37.

Obviously, the position of the third eyelet 34 may be used to control the distance between the proximal and distal stent sections 30, 31, and this distance controls the radius of curvature of the device and thus also the radius of curvature of the coronary sinus 5.

The further embodiment of the device illustrated in FIG.16 corresponds to the embodiment illustrated in FIG. 15 except that the first eyelet 32 is fixed to the proximal stent section 30 and the second eyelet 33 is fixed to the distal stent section 31. Therefore, a fourth wire 39 has the same extension as the third wire 38 in FIG. 15 but has the function of the second wire 37 in FIG. 15. A fifth wire 40 has the same extension as the second wire

15

37 in FIG. 15 but has the function of the third wire 38 of FIG. 15.

The quotient between the maximum distance and the minimum distance between the proximal stent section 30 and the distal stent section 31 in FIGS 15 and 16 is about 1.5. A quotient of about 2.5 would be possible by letting the wire 35 extend once more via the third eyelet 34 and the first eyelet 32 (or another eyelet fixed at substantially the same position as the first eyelet) before finally extending via the second eyelet 33 back to the third eyelet 34 where the second end of the wire 35 is fixed, as shown in FIG. 17.

According to FIG. 18, the wires 35-40 extending between the proximal stent section 30 and the distal stent section 31 are confined in a plastic sheath or a plastic wire spiral 41 which will cover and protect the wires 35-40. By enclosing the wires 35-40, the sheath or spiral 41 will also prohibit them from cutting through the wall of the coronary sinus 5. Alternatively, more than one sheath or spiral 41 may be used, all of which should be compressible lengthwise so as to allow the reduction of the distance between the proximal and distal stent sections 30, 31.

The embodiments illustrated in FIGS 15-18 may be introduced by conventional means into the coronary sinus 5 via the vein system. Preferably, the distal stent section 31 first is adjusted to a desired position, whereupon it is expanded so as to engage the walls of the coronary sinus 5. Thereby, the position of the distal stent section 31 is fixed in the coronary sinus 5. Then the position of the proximal stent section 30 is adjusted considering the required reduction of the distance between the proximal and distal stent sections 30, 31. Thereafter the

proximal stent section 30 is expanded such that it is fixed relative the coronary sinus 5. Finally, the distance between the proximal and distal stent sections 30, 31 is reduced using one of the wires 37 and 39. If the distance reduction is found too extensive, the distance between the stent sections 30 and 31 may be increased by pulling one of the wires 38 and 40. After achieving a perfect position, the used wires 37-40 may be removed by pulling in one of the double ends.

It should be noted that instead of eyelets having a single opening, eyelets having multiple openings could be used such that each one of the wires extends through an opening of its own.

Still one further embodiment of the device according to the present invention is illustrated in FIGS 19 and 20. Here, the device comprises an elongate body having three stent sections, the proximal stent section 30 and the distal stent section 31 being of the same type as described above. A central stent section 42 is such as to reduce its length when expanded radially.

When this device is positioned in the coronary sinus 5, the proximal and distal sections 30, 31 are first expanded, as illustrated in FIG. 19, and then the central stent section 42 is expanded. As a consequence of its length reduction when expanded, the central stent section 42 will reduce the distance between the proximal and distal stent sections 30, 31 and thus reduce the radius of curvature of the coronary sinus 5, as illustrated in FIG. 20.

Concludingly, the present invention provides a device placed in the coronary sinus 5 and designed to reduce the dilatation of the mitral annulus. This device is at a distance from the attachment of the posterior leaf-

17

let that does not much exceed the distance at which present annuloplasty rings are placed by open surgery techniques, and the coronary sinus is along its entire course large enough to hold such a device. The device could be
5 positioned by catheter technique or any other adequate technique and offers a safer alternative to the current open surgery methods. The device could be designed or heparincoated so as to avoid thrombosis in the coronary sinus, thus reducing the need for aspirin, ticlopedine or
10 anticoagulant therapy.

It is to be understood that modifications of the above-described device can be made by people skilled in the art without departing from the spirit and scope of the invention.

15

CLAIMS

1. A device for treatment of mitral annulus dilatation, comprising an elongate body having such dimensions
5 as to be insertable into the coronary sinus and having two states, in a first of which the elongate body has a shape that is adaptable to the shape of the coronary sinus, and to the second of which the elongate body is transferable from said first state assuming a reduced radius of curvature, whereby the radius of curvature of the
10 coronary sinus is reduced as well as the circumference of the mitral valve annulus, when the elongate body is positioned in the coronary sinus, said elongate body comprising a distal stent section, a proximal stent section and
15 control wires for reducing the distance between the distal and proximal stent sections.

2. The device of claim 1, wherein said control wires comprise a first wire and means for guiding said first wire in a course extending two times between the distal
20 and proximal stent sections, when the distance therebetween is at a maximum, and extending at least three times between the distal and proximal stent sections, when the distance therebetween is at a minimum.

3. The device of claim 2, wherein said guiding means
25 comprises a first eyelet fixed to one of the distal and proximal stent sections, a second eyelet fixed to the other of the distal and proximal stent sections, and a third eyelet positioned between the distal and proximal stent sections, said first wire having a first end fixed
30 to said one of the distal and proximal stent section and extending therefrom via the third eyelet, the first eyelet and the second eyelet back to the third eyelet where a second end of the first wire is fixed.

4. The device of claim 3, wherein said first eyelet is fixed to the distal stent section and said control wires comprise a second wire extending through the third eyelet and as a double wire proximally therefrom out of the coronary sinus and out of the human body.

5. The device of claim 4, wherein said control wires comprise a third wire extending through the third eyelet and as a double wire distally to and through the first eyelet and then as a double wire proximally therefrom out of the coronary sinus and out of the human body.

6. The device of claim 3, wherein said first eyelet is fixed to the proximal stent section and said control wires comprise a second wire extending through the third eyelet and as a double wire distally to and through the first eyelet and then as a double wire proximally therefrom out of the coronary sinus and out of the human body.

7. The device of claim 6, wherein said control wires comprise a third wire extending through the third eyelet and as a double wire proximally therefrom out of the coronary sinus and out of the human body.

8. The device of claim 4, wherein said first eyelet is fixed to the distal stent section and said control wires comprise a single wire having an end releasably fixed to the third eyelet and extending proximally therefrom out of the coronary sinus.

9. The device of claim 3, wherein said first wire from the first eyelet extends at least once more via the third eyelet and the first eyelet before finally extending via the second eyelet back to the third eyelet where the second end of the first wire is fixed.

10. The device of claim 1, wherein the wires extend between the stent sections in courses offset radially from a longitudinal axis of the stent sections.

11. The device of claim 1, wherein a cover encloses the wires in their courses between the distal and proximal stent sections.

12. The device of claim 11, wherein the cover comprises one or more plastic sheaths.

13. The device of claim 11, wherein the cover comprises one or more helical wires.

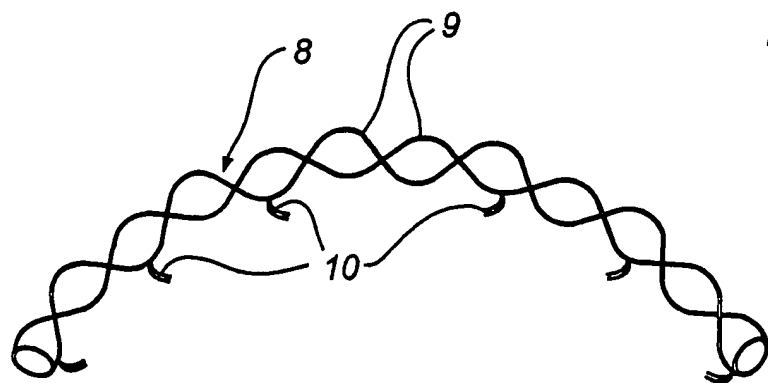
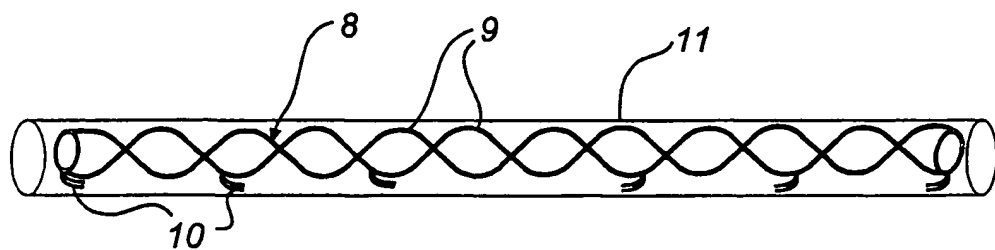
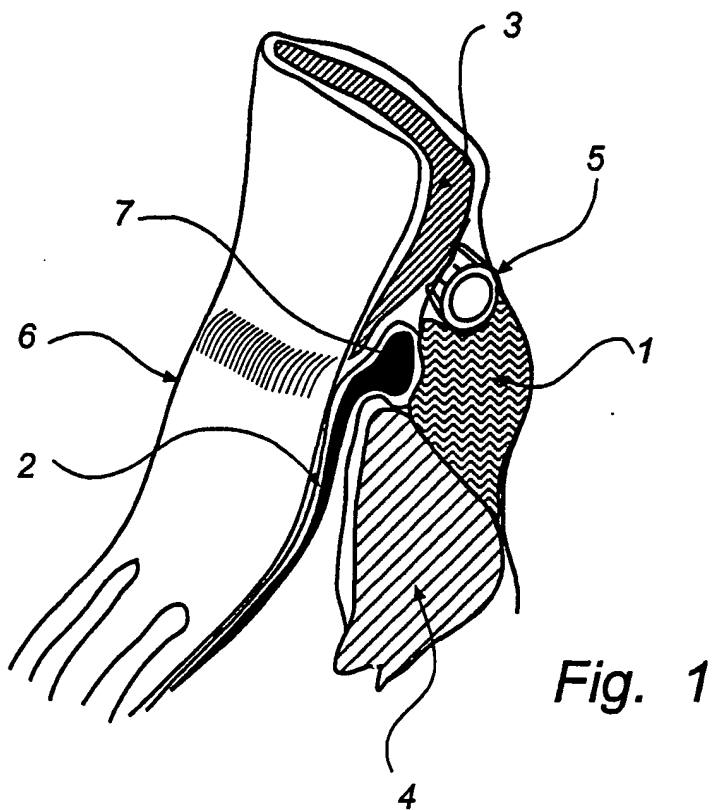
14. A device for treatment of mitral annulus dilatation, comprising an elongate body having such dimensions as to be insertable into the coronary sinus and having two states, in a first of which the elongate body has a shape that is adaptable to the shape of the coronary sinus, and to the second of which the elongate body is transferable from said first state assuming a reduced radius of curvature, whereby the radius of curvature of the coronary sinus is reduced as well as the circumference of the mitral valve annulus, when the elongate body is positioned in the coronary sinus, said elongate body comprising at least one stent section at a distance from each end of the elongate body, said stent section providing a reduction of its length when expanded in situ in the coronary sinus, whereby the elongate body is shortened and bent to a smaller radius of curvature.

15. The device of claim 14, wherein the elongate body comprises a distal stent section, a proximal stent section and a central stent section, the distal and proximal stent sections being expandable prior to the central stent section.

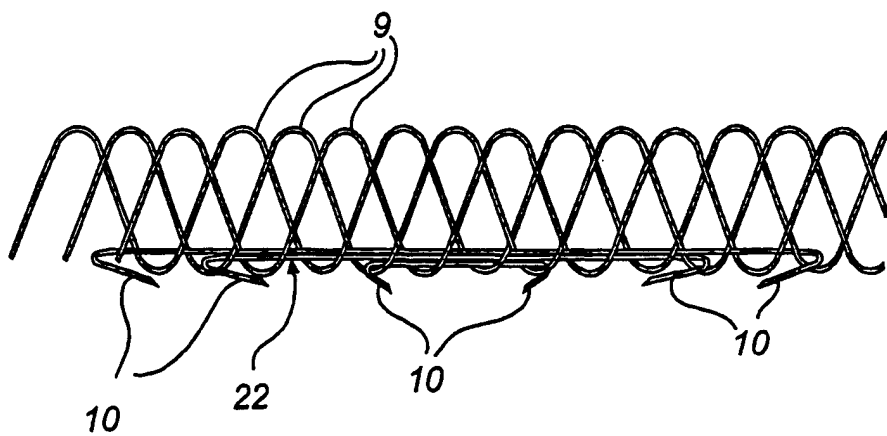
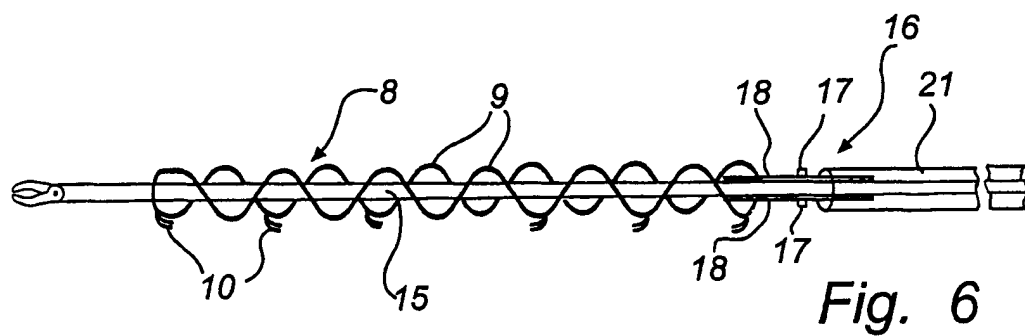
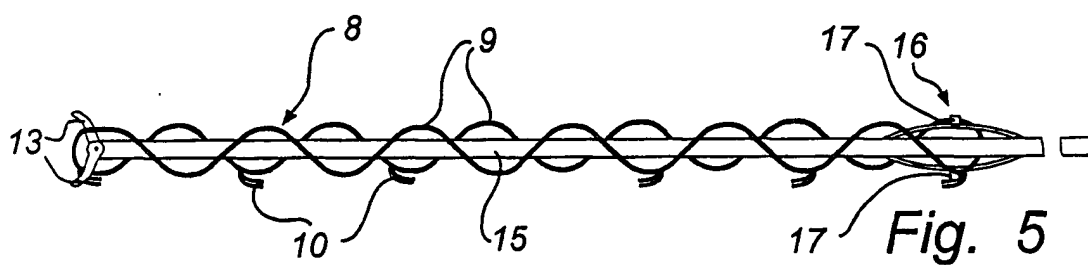
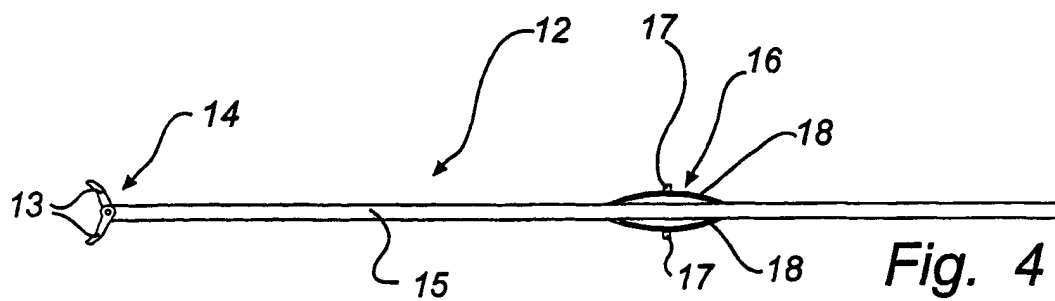
16. The device of claim 15, wherein the distal and proximal stent sections are expandable without substantial length reduction.

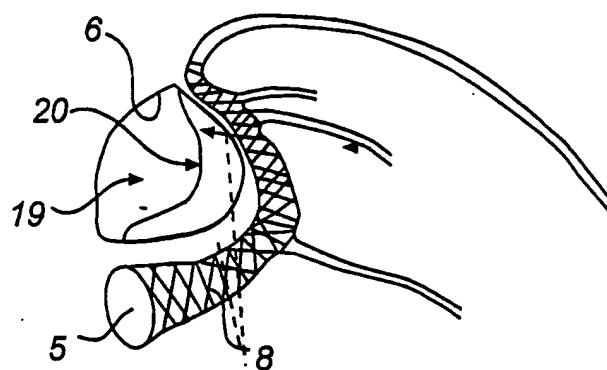
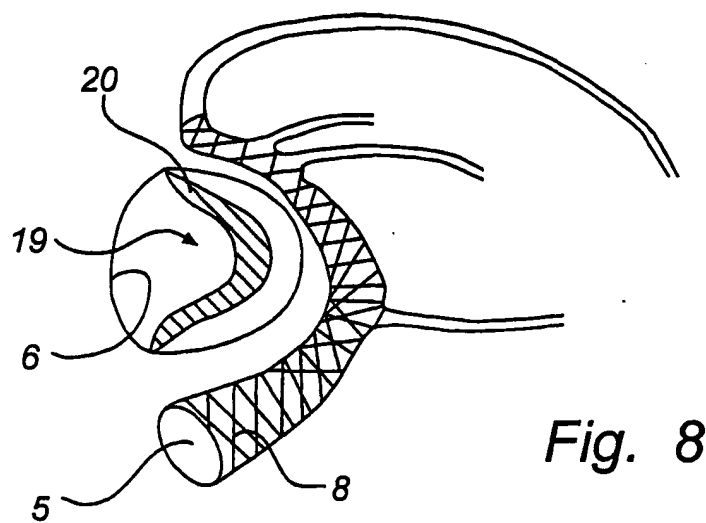
17. The device of claim 14, wherein a memory material is used as stent material.

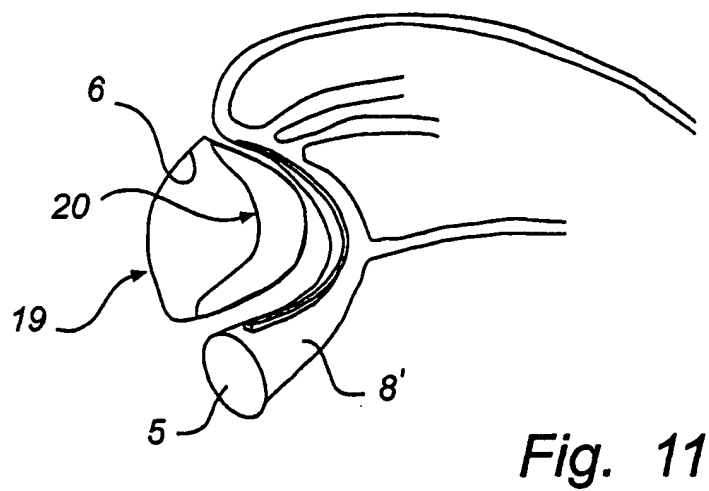
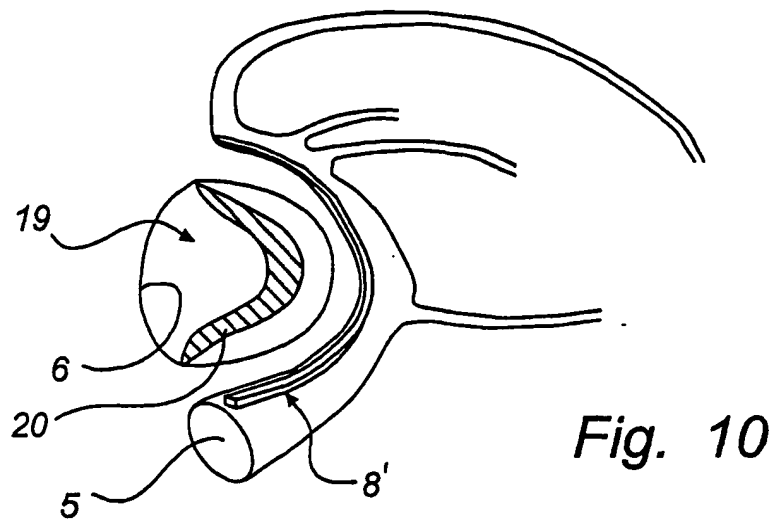
1/7



2/7







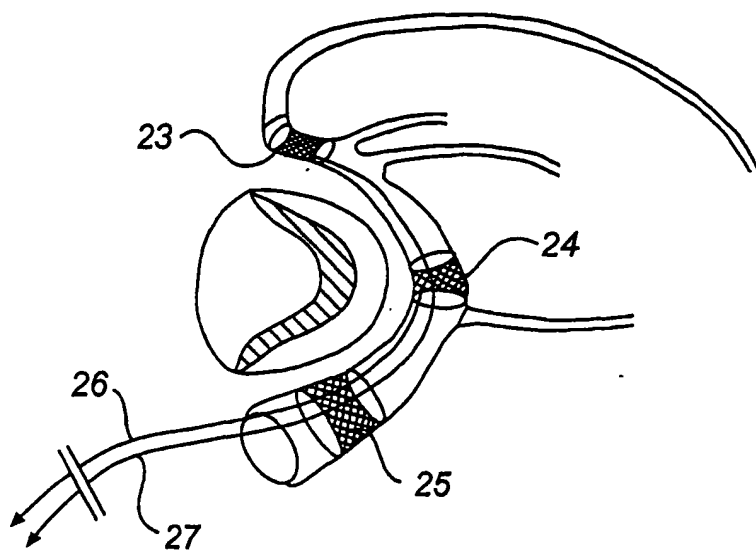


Fig. 12

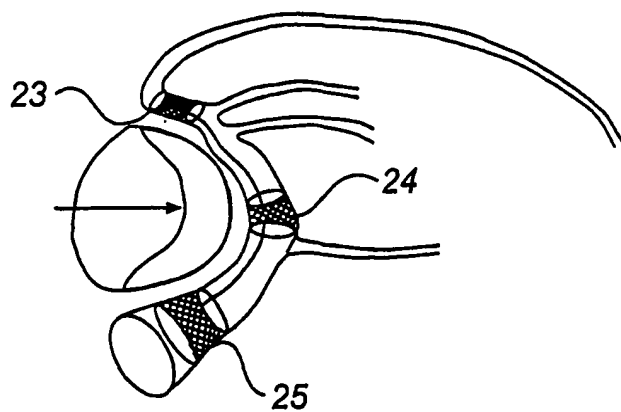


Fig. 13

6/7

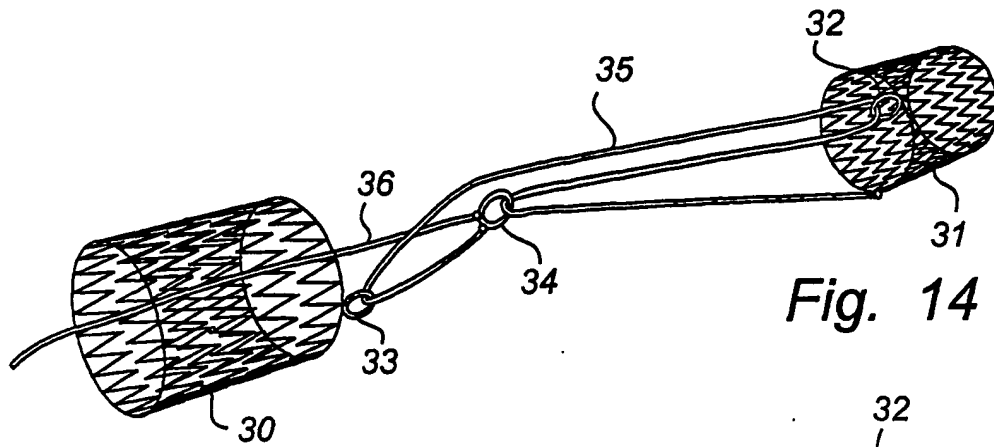


Fig. 14

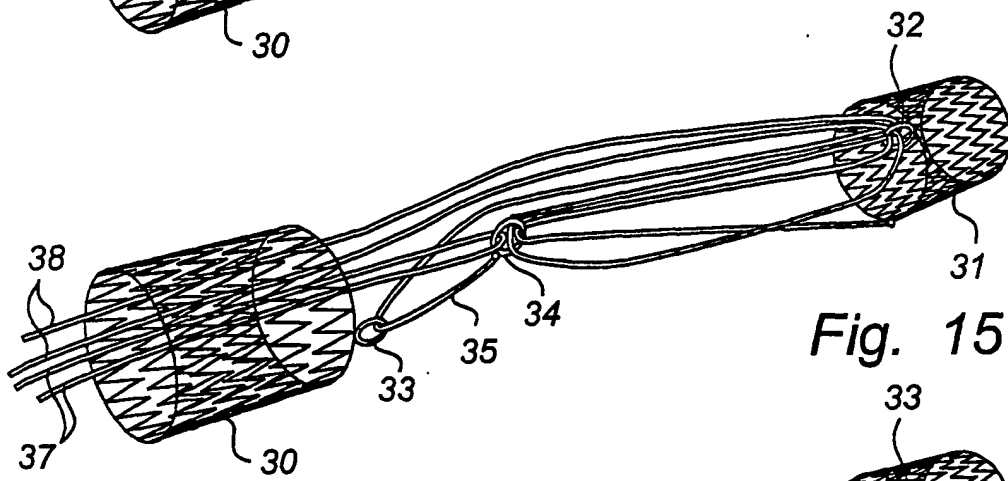


Fig. 15

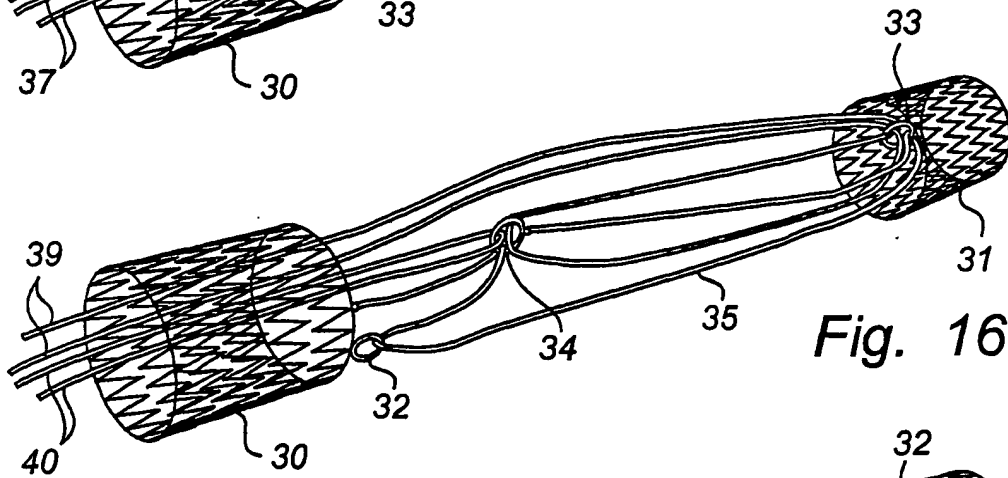


Fig. 16

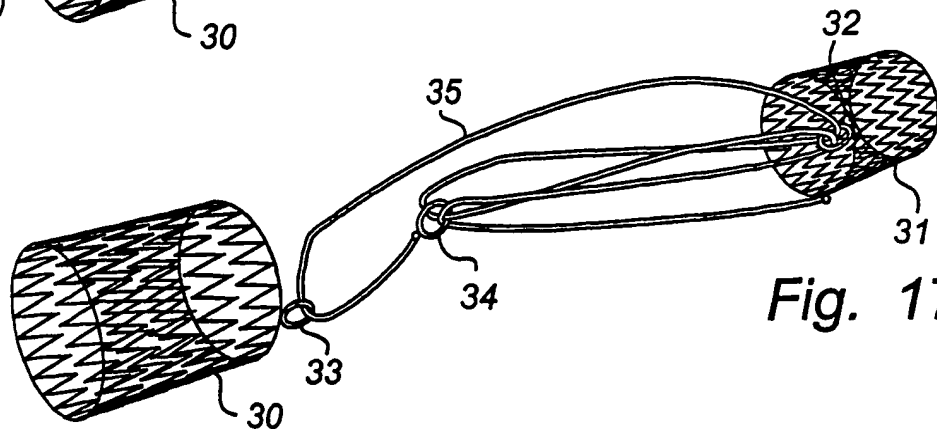


Fig. 17

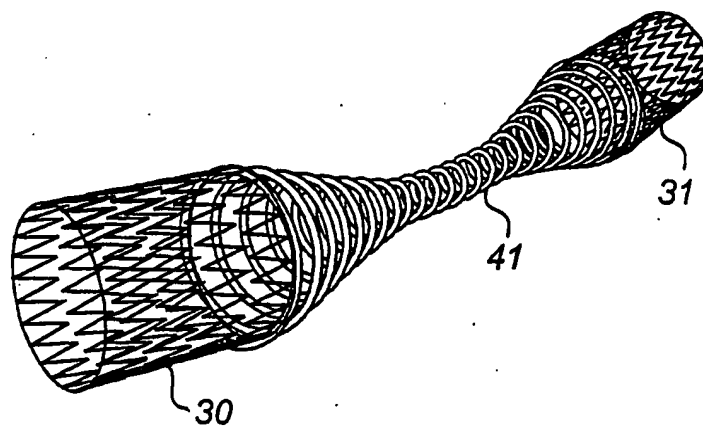


Fig. 18

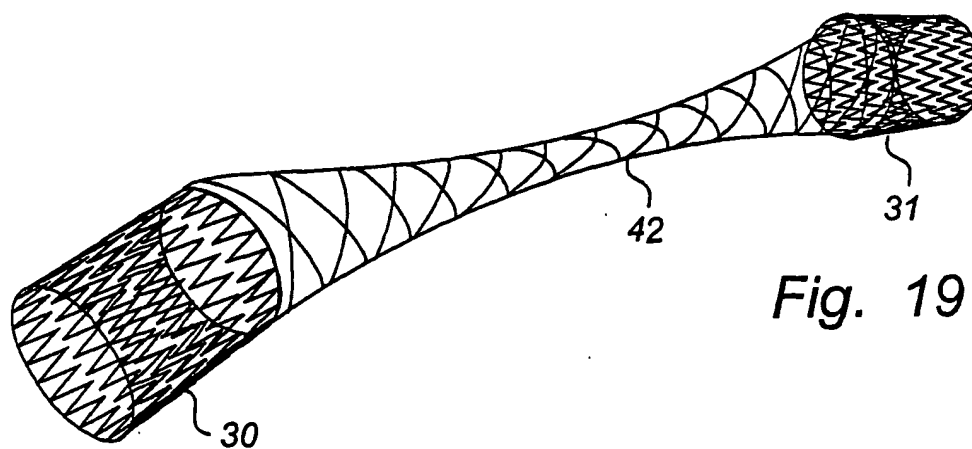


Fig. 19

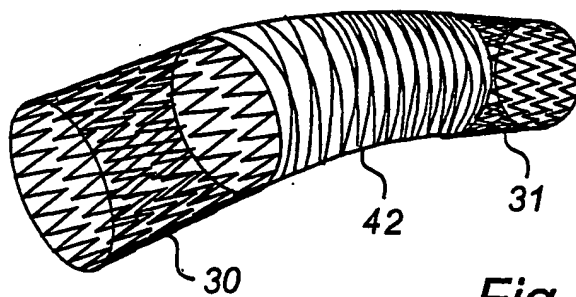


Fig. 20

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/EP 01/10371

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 383 892 A (ANSEL DENIS ET AL) 24 January 1995 (1995-01-24) column 1, line 33 - line 47; claim 1; figures 1,2	14,15,17
A	---	1
X	US 5 064 435 A (PORTER CHRISTOPHER H) 12 November 1991 (1991-11-12) column 5, line 13 - line 33; figures 1,2	14,15,17
A	---	1,14,17
A	US 5 980 552 A (PINCHASIK GREGORY ET AL) 9 November 1999 (1999-11-09) column 2, line 3 - line 18; figures 3A,3B	1,14
A	US 5 911 732 A (HOJEIBANE HIKMAT) 15 June 1999 (1999-06-15) column 7, line 34 - line 42; figure 3	1,14
	--- -/-	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the International filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the International filing date but later than the priority date claimed

T later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

Z document member of the same patent family

Date of the actual completion of the International search

11 April 2002

Date of mailing of the International search report

23/04/2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Ducreau, F

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 01/10371

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 196 11 755 A (MEYER JOERG) 5 February 1998 (1998-02-05) the whole document ---	1,14
A	EP 0 727 239 A (DAIG CORP) 21 August 1996 (1996-08-21) abstract; figure 2A -----	1,14

INTERNATIONAL SEARCH REPORT
Information on patent family members

International Application No
PCT/EP 01/10371

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5383892	A	24-01-1995	FR 2683449 A1	14-05-1993
			AT 133554 T	15-02-1996
			CA 2082367 A1	09-05-1993
			DE 69208026 D1	14-03-1996
			DE 69208026 T2	05-09-1996
			DK 541443 T3	03-06-1996
			EP 0541443 A1	12-05-1993
			ES 2085595 T3	01-06-1996
US 5064435	A	12-11-1991	AT 102466 T	15-03-1994
			CA 2086333 A1	29-12-1991
			DE 9190098 U1	01-04-1993
			DE 69101385 D1	14-04-1994
			DE 69101385 T2	16-06-1994
			DK 536164 T3	09-05-1994
			EP 0536164 A1	14-04-1993
			ES 2050054 T3	01-05-1994
			JP 6036807 B	18-05-1994
			WO 9200043 A1	09-01-1992
US 5980552	A	09-11-1999	US 5449373 A	12-09-1995
			US 6059811 A	09-05-2000
			CA 2219488 A1	31-10-1996
			US 5972018 A	26-10-1999
			WO 9633671 A1	31-10-1996
			US 2001018595 A1	30-08-2001
			US 5733303 A	31-03-1998
			US 5843120 A	01-12-1998
			US 2002010506 A1	24-01-2002
US 5911732	A	15-06-1999	AU 5738598 A	10-09-1998
			CA 2231502 A1	10-09-1998
			EP 0864302 A2	16-09-1998
			JP 11019219 A	26-01-1999
			US 6238409 B1	29-05-2001
			US 2001016769 A1	23-08-2001
DE 19611755	A	05-02-1998	DE 19611755 A1	05-02-1998
EP 0727239	A	21-08-1996	US 5640955 A	24-06-1997
			CA 2150784 A1	15-08-1996
			CA 2153178 A1	15-08-1996
			EP 0727238 A2	21-08-1996
			EP 0727239 A2	21-08-1996
			JP 8266550 A	15-10-1996
			JP 9047513 A	18-02-1997
			US 6156018 A	05-12-2000
			US 5868733 A	09-02-1999
			US 5814029 A	29-09-1998
			US 2001005783 A1	28-06-2001
			US 6203531 B1	20-03-2001

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.